REMARKS

Claims 1-9, 12, 13 and 38 are pending in the subject application. By this Amendment, applicant has canceled claims 1-9, 12, 13 and 38 and added new claims 91-98. New claim 91 corresponds to canceled claims 1, 16 and 23. New claim 92 is supported in the specification at, *inter alia*, page 15, lines 11-14. New claim 93 is supported in the specification, *inter alia*, at page 15, lines 14-15. New claim 94 corresponds to canceled claim 24. New claim 95 corresponds to canceled claim 25. New claim 96 corresponds to canceled claim 26. New claim 97 corresponds to canceled claim 27. New claim 98 corresponds to canceled claim 37. Applicant maintains that the addition of new claims 91-98 raises no issue of new matter and is fully supported by the specification as filed. Accordingly, claims 91-98 will be pending and under examination upon entry of this Amendment.

In view of the arguments set forth below, applicant maintains that the Examiner's rejections made in the November 4, 2004 Office Action have been overcome, and respectfully requests that the Examiner reconsider and withdraw same.

Formalities

The Examiner stated that a proper abstract on a separate page must be submitted. In response, applicant annexes hereto as **Exhibit A** an abstract for the instant application. Applicant asserts that the abstract does not raise any issue of new matter, and that the abstract is fully supported by the specification as filed.

Applicant also acknowledges the Examiner's remarks regarding priority, without conceding their correctness. Applicant reserves the right to traverse the Examiner's remarks later should applicant's priority claim be denied.

Double Patenting Rejection

The Examiner rejected original claims 1-9, 12, 13 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-57 of copending Application No. 09/474,478, because the conflicting claims are not patentably distinct from each other. Applicant addresses the rejection as applied to new claims 91-98.

In response, applicant will consider submitting a terminal disclaimer at such time as the instant claims are deemed otherwise allowable.

Rejection Under 35 U.S.C. §103(a) - Obviousness

The Examiner rejected claims 1-9, 12, 13 and 38 under 35 U.S.C. §103(a) as allegedly unpatentable over Columbo (J. of Immunology) in view of Mohammadi (Science). Applicant addresses the rejection as applied to new claims 91-98.

In response, applicant points out that claims 1-9, 12, 13 and 38 have been canceled, rendering the Examiner's rejection thereof moot. Applicant understands the rejection to apply to new claims 91-98, and respectfully traverse the rejection. Applicant maintains that the Examiner has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, must teach or suggest each element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Claims 91-98 provide a method for treating or preventing contact dermatitis. This method comprises administering to a subject an amount of an antibody that binds to kit protein, thereby treating or preventing contact dermatitis.

Columbo teaches a human recombinant c-kit receptor ligand stem cell factor (rhSCF) and its effects on the release of inflammatory mediators from human skin mast cells and peripheral blood basophils *in vitro*. Nowhere is it suggested that anti c-kit receptor ligand or antibody can be used *in vivo* to treat or prevent *any* disease, let alone contact dermatitis, via blocking the SCF-KIT signaling pathway.

Mohammadi does nothing more than disclose a new class of protein tyrosine kinase inhibitors based on an oxindole core (indolinones) and its effect on fibroblast growth factor receptor 1 (FGFR1) in NIH 3T3 cells. Although Mohammadi states that selective inhibitors of protein tyrosine kinases have considerable therapeutic value, this statement, at most applies solely to the treatment of some forms of cancer, such as glioma, through the use of indolinones. (Mohammadi, page 959). Nowhere is it suggested that indolinones are anti-c-kit

ligands or that an anti-c-kit ligand can be used to prevent or treat *any* disease, let alone contact dermatitis *in vivo*.

Finally, applicant maintains that the Examiner has applied hindsight in concluding that the claimed invention is obvious. Specifically, it was applicant's own *in vivo* experiments which demonstrated the *surprising* effect of anti-kit-antibody on a contact dermatitis model. It is untenable for the Examiner to now maintain that these data would have been predictable, absent undue experimentation. Indeed, the tenor of the Examiner's own remarks regarding undue experimentation underscores applicant's position, i.e., "[t]he difficulty in performing the claimed functions [of preventing or treating the enumerated disorders] is well known in the art." (page 5 of the Office Action).

In view of the above remarks, applicant maintains that new claims 91-98 satisfy the requirements of 35 U.S.C. §103(a).

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-9, 12, 13 and 38 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states that undue experimentation would be needed to determine what compounds would be effective in inhibiting the stem cell factor signaling pathway and effectively preventing or treating the claimed disorders.

In response, applicant points out that claims 1-9, 12, 13 and 38 have been canceled, rendering the Examiner's rejection therof moot. Applicant understands the rejection to apply to new claims 91-98 and respectfully traverses the rejection. Applicant states that new claims 91-98 are not drawn to all compounds generally, but rather are specifically directed to antibodies or portions thereof that can inhibit the kinase enzymatic reaction of kit protein and thus inhibit the stem cell factor signaling pathway. Therefore, applicant maintains that claims 91-98 are enabled.

In view of the above remarks, applicant maintains that new claims 91-98 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-9, 12, 13 and 38 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that the phrase a "compound capable of" in claim 1 is improper because compounds do not have capabilities. The Examiner further states that there is inconsistency between hypersensitivity reactions and urticaria in claim 8.

In response, applicant points out that claims 1-9, 12, 13 and 38 have been canceled, rendering the Examiner's rejection therof moot. Applicant understands the rejection to apply to new claims 91-98 and respectfully traverses the rejection.

Specifically, applicant notes that new claims 91-98 do not contain the language objected to by the Examiner, thereby obviating the Examiner's rejection.

In view of the above remarks, applicant maintains that new claims 91-98 satisfy the requirements of 35 U.S.C. §112, second paragraph.

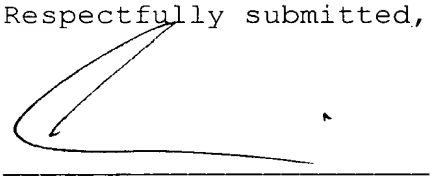
Summary

Applicant maintains that the claims pending are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450

2/4/03
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